JUL 2 2 2004

510(k) Summary
LPS Dovetail Intercalary

K041085

A. Contact Person:

Tiffani Rogers
Regulatory Affairs
TEL: (574) 371-4927, FAX (574) 371-4987, EMAIL TRogers1@dpyus.jnj.com

B. Device Information:

Trade Name:	LPS (Limb Preservation System) Lower Extremity Dovetail Intercalary
Common Name:	Total Knee Prosthesis
Classification Name and Regulatory Class:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis: Class II per 21 CFR §888.3560
Product Code:	87 JWH

C. Indications for Use:

The LPS Intercalary component is intended for use in primary and revision knee joint replacement and in oncology cases with the Limb Preservation System (LPS). The previously cleared indications for use for this systems are the following:

The Limb Preservation System (**LPS**) is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

- malignant tumors (e.g., osteosarcoma, chondrosarcoma, giant cell tumors, bone tumors) requiring extensive resection and replacement;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
- revision cases for a failed previous prosthesis requiring extensive resection and replacement;
- severe trauma requiring extensive resection and replacement.

The LPS is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The distal femoral component, the tibial components, tibial stems, metaphyseal sleeves, and the non-porous coated straight and bowed stems are intended for cemented use only.

510(k) Summary (continued)
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D. Device Description:

The intercalary component serves as a segmental component in the previously cleared Limb Preservation System (LPS, K003182). The dovetail intercalary component is a 3-piece assembly 55 mm in length. The three pieces are comprised of a male segment, a female segment and a connecting pin. The male-female parts connect as a dovetail connection and locked with a pin screwed through both segments. The dovetail intercalary component is made of cobalt chrome.

E. Substantial Equivalence:

The substantial equivalence of the LPS Dovetail Intercalary is substantiated by its similarity in sterilization, packaging and indications for use to the LPS (K003182 cleared on June 27, 2001). The design and materials of the LPS Dovetail Intercalary have been modified from the existing LPS Intercalary component cleared in K003182, however DePuy believes this new component is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2004

Tiffani D. Rogers
Regulatory Affairs Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K041085
Trade/Device Name: LPS Lower Extremity Dovetail Intercalary
Regulation Numbers: 21 CFR 888.3560
Regulation Names: Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: April 23, 2004
Received: April 26, 2004

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041085

Device Name: **LPS Lower Extremity Dovetail Intercalary**

Indications for Use:

The LPS Intercalary component is intended for use in primary and revision knee joint replacement and in oncology cases with the Limb Preservation System (LPS). The previously cleared indications for use for this system are the following:

The **LPS** is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

- malignant tumors (e.g., osteosarcoma, chondrosarcoma, giant cell tumors, bone tumors) requiring extensive resection and replacement;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
- revision cases for a failed previous prosthesis requiring extensive resection and replacement;
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The LPS is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The distal femoral component, the tibial components, tibial stems, metaphyseal sleeves, and the non-porous coated straight and bowed stems are intended for cemented use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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